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FAX NO. 2013431684

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PATENT
601-1-057NIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Johnson et al.

SERIAL NO. : 09/577,266
FILED : May 23, 2000EXAMINER : Moran, Marjorie A.
ART UNIT : 1631FOR : METHODS FOR DIAGNOSING, PREVENTING AND TREATING
DEVELOPMENTAL DISORDERS DUE TO A COMBINATION OF
GENETIC AND ENVIRONMENTAL FACTORSCERTIFICATE OF MAILING UNDER 37 C.F.R. 1.4

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 03/03/04

Christine B. Dietsel, Reg. No. 37,300
(Name of Registered Representative)

Signature and Title

DECLARATION PURSUANT TO 37 C.F.R. 1.131 OF
WILLIAM JOHNSON, M.D.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, William Johnson, M.D., do hereby declare as follows:

- (1) That my address is: 91 Stewart Road
Short Hills, NJ 07078
- (2) That I am an inventor of the subject application;
- (3) That the subject application was filed with the U.S. PTO on May 23, 2000,
claiming priority to an earlier application U.S.S.N 60/156,198 filed May 25, 1999;
- (4) That I have reviewed the reference Christensen, B. et al (1999) Am J Med
Genet May 21; 84(2):151-7 entitled "Genetic Polymorphisms in Methylene-tetrahydrofolate
Reductase and Methionine Synthase, Folate Levels in Red Blood Cells, and Risk of Neural

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Tube Defects", cited by the Examiner in the subject application in the Office Action dated October 15, 2003, which Christensen reference is reported as being published online April 16, 1999, pursuant to the attached online Abstract;

[5] That the invention described and claimed in the subject invention was conceived and reduced to practice in the United States prior to the effective date of the Christensen et al reference, and particularly prior to April 16, 1999, as evidenced by the attached Exhibit;

[6] That the Exhibit is a letter from myself to my attorney Michael Davis of Klauber & Jackson, detailing three manuscripts which disclose and describe the invention of the subject application and providing said manuscripts; and;

[7] That the article Christensen, B. et al. (1999) Am J Med Genet May 21; 84(2):151-7, cited by the Examiner is therefore not prior art under 35 U.S.C. §102(a) or (e) and is not suitable as a §103 reference for anticipation or obviousness.

[8] I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2/27/04
Date


William Johnson, M.D.